REMARKS

Applicants propose to amend Claims 1 and 20, the only independent claims pending in the application, to overcome the rejection under 35 U.S.C. §112. The limitation that the free hyaluronic acid is suitable for use in the body has been moved from the preamble to the body of the claim. Applicants intend that this limitation be part of the claimed invention.

Applicants submit that the proposed amendment does not raise a new issue, as it relates only to a rejection under Section 112, and simply clarifies what has already been repeatedly discussed during the prosecution of this case. Moreover, the Examiner's rejection implies that the Examiner has already interpreted the claims to include this limitation. Applicants also submit that the proposed amendment places the application in better form for appeal. For all of these reasons, Applicants believe that this Amendment should be entered.

The Examiner has rejected the claims under 35 U.S.C. §103 over the patent to Schultz.

The Examiner's argument appears to be in two parts. First, the Examiner states that Schultz discloses hyaluronic acid that can be administered to animals and humans. Secondly, the Examiner holds that Applicants have not shown that the claimed product yields unexpected results. Applicants respond to both of these arguments in the following paragraphs.

1. The Patent to Schultz

Applicants submit that Schultz is inapplicable because the patent, by its own admission, does not use free hyaluronic acid. The patent admits, in column 4, line 67, through column 5, line 6, that all of the examples provided in the patent were developed with sodium hyaluronate, not free hyaluronic acid. Moreover, the patent proposes to label both the free-acid form and the salt form with the single name of "hyaluronic acid" (col. 5, lines 5-6), thus perpetuating an inaccuracy that has plagued the field for many years.

Schultz provides no more than a conjecture that free hyaluronic acid could be used. Schultz clearly did not use free hyaluronic acid in making the invention, and provides no direction on how to make or obtain that product. Absent such a teaching, Schultz is of no relevance to the patentability of the present invention.

Applicants note further that, in the first Declaration of Ellington M. Beavers, filed with the present application on July 17, 1998, it was explained that free hyaluronic acid could be made in different ways, and that not all such products are the same. In particular, Dr. Beavers showed that if hyaluronic acid were made by methods other than the claimed method, the result would not be the same product, because it would not be of medical grade. Therefore, the properties of the product depend critically on the method of manufacture. Since Schultz contains no teaching of how a free-acid form of hyaluronic acid could be made, Schultz cannot be considered to anticipate or suggest the present claimed invention.

For all of the above reasons, Applicants submit that Schultz is not a pertinent reference, and that the rejection over Schultz should be withdrawn.

2. Unexpected Results

To appreciate the unexpected results of the free hyaluronic acid of the present invention, one must first recall that the relevant industry, until now, has not even recognized a significant difference between hyaluronic acid (the free acid) and sodium hyaluronate. As explained more fully in the previous Amendment, the literature is filled with references to "hyaluronic acid" when what is meant is really "sodium hyaluronate".

Indeed, the patent to Schultz, now the only reference applied to the claims, proposes ("for convenience" (see col. 5, line 5)) to use the term "hyaluronic acid" to include both the free acid and the sodium salt.

The attached Third Declaration of Ellington M. Beavers, one of the Applicants, provides another graphic illustration of the extent of the misconception as it exists in the industry even now. Paragraphs 11 and 12 of this Declaration relate a recent incident in which Dr. Beavers ordered a quantity of sodium hyaluronate from a chemical supplier. The supplier confirmed the order, not for sodium hyaluronate, but for "hyaluronic acid powder". The product arrived, and the Certificate of Analysis that accompanied the product clearly stated that the product was sodium hyaluronate.

Thus, for practical purposes, hyaluronic acid and sodium hyaluronate have been considered equivalent by the industry, and by academic researchers.

Applicants, however, have discovered a free-acid form of the product, having properties that make it suitable for temporary or permanent use in the body, and also that make it much more practical for use in forming hydrophilic and lubricious coatings.

Paragraphs 3-9 of the attached Declaration explain the special benefits obtained from the free hyaluronic acid of the present invention. As set forth more fully in the Declaration, the details of which will not be repeated here, the medical-grade free hyaluronic acid of the present invention makes it possible to use polyaziridine as part of the tie-coat (the coating that sits between the underlying substrate and the coating of hyaluronic acid), and makes it practical to use an aqueous emulsion polymer as the tie-coat. The sodium salt form cannot be so used. The free hyaluronic acid of the present invention also has the unexpected property that it can join with other molecules of itself, in the presence of polyaziridine, to make a much stronger coating. The sodium salt cannot be used in the same way.

The facts outlined in the Declaration of Dr. Beavers were not generally known at the time the invention was made. In fact, the advantages of the free-acid form of hyaluronic acid are not widely appreciated. In the prior art, there was no reason to believe that the free-acid form would have any particular advantages over the sodium salt, and thus almost everyone in the industry, and in the academic world, referred to both substances with the same name. It was due to Applicants' discovery that the distinction between the free acid and the sodium salt has become much more clear. Applicants have discovered a product that has a surprising and unexpected result, and which is not available from any known source.

In summary, Applicants have invented a medical-grade free-acid form of hyaluronic acid. The claimed product is different from any known product of the prior art. The claimed free-acid form of the product also has significant advantages over the sodium salt used in the prior art.

These advantages were not apparent to those of ordinary skill, but were first recognized by Applicants in the course of making their invention.

For the reasons given above, Applicants submit that the application, as amended, is in condition for allowance. Applicants request reconsideration, entry of this Amendment, and early favorable action, by the Examiner. If the Examiner has questions, Applicants request that he telephone the undersigned to expedite the prosecution of this case.

Respectfully submitted,

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